

REMARKS/ARGUMENT

Description of Amendments

Claim 23 has been amended to include elements of claims 27 and 51, which are now canceled.

Claim 41 has been amended to include elements of claim 43.

Claim 53 was amended to be consistent with changes to claim 23.

No new matter has been introduced. Support for “release” of active ingredients can be found throughout the originally-filed specification (see, for example, paragraph 22 of Pub. No. 2004/0073298).

Reconsideration and withdrawal of the rejections are respectfully requested in view of the foregoing amendments and the remarks presented below.

Rejection under 35 U.S.C. §112

Claims 23, 24, 27-39, and 41-45, 48, 50-53 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

The Office took issue with elements associated with “a solvent” recited in the claims. Applicant has amended the claims to delete elements associated with the solvent and trusts that such amendments overcome the rejection.

Rejection under 35 U.S.C. §103

I. Rejections over Alt in view of Georger and Tang

Claims 23, 27, 29, 30-42, 34-37, 39, 41, 45, 51 and 53 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,788,979 (“Alt”) in view of U.S. Patent U.S. Patent 5,510,628 (“Georger”) and U.S. Patent 5,412,068 (“Tang”).

Claims 27, 34, 37 and 51 have been canceled, rendering their rejection moot. The only independent claims remaining are claims 23 and 41, which are currently amended.

Alt, Georger, and Tang, individually and if combined, fail to meet the following elements in the last clause of claim 23:

a discontinuous second layer having a segment separated by the first layer, the second layer made of a second polymer, wherein the first and second layers do not radially overlap each other, and wherein the first layer contains a first active ingredient and is adapted to release the first active ingredient, and wherein the second layer contains a second active ingredient and is adapted to release the second active ingredient.

Alt, Georger, and Tang, individually and if combined, fail to meet the following elements in the last clause of claim 41:

the polymeric coating includes alternating sections of a first layer and a second layer arranged along a segment of the substrate, the first and second layers do not overlap radially, and wherein the first layer contains a first active ingredient and is adapted to release the first active ingredient, and wherein the second layer contains a second active ingredient and is adapted to release the second active ingredient.

The Office stated that “Alt does not expressly disclose alternating back and forth between layers and thus discontinuous layers,” but that “such an alternating configuration is known in the art in view of Georger” (Office Action, p. 3). The Office concluded that it would have been obvious for one of ordinary skill in the art to modify Alt by a “simple substitution of one known configuration for another wherein a single coating layer is formed of multiple sections having different compositions” (Office Action, p. 3).

The Office’s proposed substitution must have predictable results (see MPEP 2143.01). The Office asserted in the Advisory Action that results are predictable but provided no support. There is strong evidence that such a substitution would be unsuccessful or, at the very least, have unpredictable results.

Georger is generally directed to “ultra-thin films for selective adhesion and outgrowth of cells” (col. 8:1-8). An ultra-thin film of a particular cell adhesion molecule, such as $\text{NHCH}_2\text{CH}_2\text{NH}_2$, is patterned by exposing it to ultraviolet light of a particular intensity or wavelength to create areas devoid of the molecule. At a later time, the remaining cell adhesion molecules can attract certain biological cells. By contrast, Alt is generally directed to a coating that carries and releases a drug. The drug is carried by poly-D,L-lactid or “any

biodegradable coating material ... [that] dries relatively rapid to a self-adhesive lacquer – or paint-like coating” (col. 7:50-58). The self-adhesive lacquers and paint-like coatings in Alt, which are applied by spraying or dipping (Alt, col. 4:12), are much thicker than Georger’s ultra-thin films which are one molecule thick (Georger FIG. 1c) or even a few molecules thick. Alt’s carrier coatings can have a thickness on the order of micrometers (Alt col. 4:4) whereas Georger’s ultra-thin films have a thickness on the order of nanometers (Georger col. 13:14), which means that Alt’s carrier coatings are a thousand times thicker than Georger’s ultra-thin films. There is no indication in Georger and Alt that ultraviolet light can be used to completely remove areas of Alt’s self-adhesive lacquers and paint-like coatings down to the substrate. Since Alt’s self-adhesive lacquers and paint-like coatings are a thousand times thicker than Georger’s ultra-thin coatings, Applicant submits that a person of ordinary skill in the art would not reasonably expect that the application of ultraviolet light could remove self-adhesive lacquers and paint-like coatings.

The Office cited Georger’s FIGS. 1c and 5a. FIG. 1c shows a glass microscope slide covered by a single molecule layer of cell adhesion promoters and cell adhesion inhibitors. FIG. 5a shows a rolled sheet of biocompatible material having alternating spacers (2) and strips of cell adhesion promoters and adhesion inhibitor regions (3). Neither the cell adhesion promoters, cell adhesion inhibitors, nor spacers carry a drug that is later released, unlike the lacquers and paint-like coatings in Alt. Also, instead of releasing a substance, the cell adhesion promoters attract biological cells. These differences indicate that Alt’s carrier coatings are very different from Georger’s ultra-thin films in terms of chemical composition and structure, which would have further cast doubt in the mind of a person of ordinary skill in the art on the effectiveness of ultraviolet light in removing Alt’s carrier coatings down to the substrate.

In sum, the Office’s proposed substitution does not have predictable results. Applicant respectfully submits that independent claims 23 and 41 are patentably allowable over Alt in view of Georger. Tang fails to cure the deficiencies of Alt and Georger with respect to claims 23 and 41. Therefore, claims 23 and 41 are also patentably allowable over Alt in view of Georger and Tang.

The remaining claims rejected over Alt in view of Georger and Tang depend from base claims 23 and 41, include all the elements of their respective base claim, and are

therefore patentably allowable over Alt in view of Georger and Tang for at least the same reasons given above for claims 23 and 41.

II. Rejections over Alt in view of Georger, Tang, and Fearnot

Claims 24, 28, 38, 42, 44, 48, 50 and 52 were rejected under 35 U.S.C. §103(a) as being unpatentable over Alt in view of Georger and Tang as applied to claims 23 and 41 and further in view of U.S. Patent 5,609,629 “(Fearnot)”.

Claim 38 has been canceled, rendering its rejection moot.

As indicated above, independent claims 23 and 41 are patentably allowable over Alt in view of Georger and Tang. Fearnot fails to cure the deficiencies of Alt, Georger and Tang with respect to claims 23 and 41. Therefore, claims 23 and 41 are also patentably allowable over Alt in view of Georger and Tang and further in view of Fearnot.

Claims 24, 28, 42, 44, 48, 50 and 52 are depend from base claims 23 and 41, include all the elements of their respective base claim, and are patentably allowable over Alt in view of Georger and Tang and further in view of Fearnot for at least the same reasons that their respective claim is patentably allowable.

III. Rejections over Alt in view of Georger, Tang, and Ding

Claims 33 and 43 were rejected under 35 U.S.C. §103(a) as being unpatentable over Alt in view of Georger and Tang as applied to claims 23 and 41 and further in view of U.S. Patent 5,837,313 “(Ding)”.

Claim 33 has been canceled, rendering its rejection moot.

As indicated above, independent claims 23 and 41 are patentably allowable over Alt in view of Georger and Tang. Ding fails to cure the deficiencies of Alt, Georger and Tang with respect to claims 23 and 41. Therefore, claims 23 and 41 are also patentably allowable over Alt in view of Georger and Tang and further in view of Ding.

Claims 43 depends from base claim 41, include all the elements of claim 41, and is patentably allowable over Alt in view of Georger and Tang and further in view of Ding for at least the same reasons that claim 41 is patentably allowable.

IV. Rejections over Alt in view of Georger, Tang, Ding, and Fearnot

Claim 44 was rejected under 35 U.S.C. §103(a) as being unpatentable over Alt in view of Georger, Tang and Ding as applied to claim 43 and further in view of Fearnot.

As indicated above independent claim 41 is patentably allowable over Alt in view of Georger, Tang and Ding. Fearnot fails to cure the deficiencies of Alt, Georger, Tang, and Ding with respect to claim 41. Therefore, claim 41 is also patentably allowable over Alt in view of Georger, Tang, and Ding and further in view of Fearnot.

Claim 44 depends from base claim 41, includes all the elements of claim 41, and is patentably allowable over Alt in view of Georger, Tang, and Ding and further in view of Fearnot for at least the same reasons that claim 41 is patentably allowable.

Conclusion

In light of the foregoing amendments and remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

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